

Patient Information Leaflet  
**Difflam 0.15% Oral Rinse**  
Benzydamine hydrochloride



Code 422

**Read all of this leaflet carefully because it contains important information for you.**

- This medicine is available without prescription. However, you still need to use it carefully to get the best results.
- Keep this leaflet. You may need to read it again.
- Ask your doctor, dentist or pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.

**In this leaflet:**

1. What Difflam Oral Rinse is for
2. Before you use Difflam Oral Rinse
3. How to use Difflam Oral Rinse
4. Possible side effects
5. How to store Difflam Oral Rinse
6. Further information.

**1. What Difflam Oral Rinse is for**

Difflam Oral Rinse belongs to a group of medicines called non-steroidal anti-inflammatory drugs or NSAIDS.

Difflam Oral Rinse works by stopping pain and swelling (inflammation). It is used to treat many painful conditions of the mouth or throat including:

- Mouth ulcers
- Sore throat
- Discomfort associated with dentures or dental work.

**2. Before you use Difflam Oral Rinse**

**Do not use Difflam Oral Rinse if**

- you are allergic to benzydamine hydrochloride
- you are allergic to any of the other ingredients of Difflam Oral Rinse (see section 6).

**Take special care:**

- If you have a history of asthma
- If you are allergic to acetylsalicylic acid or other non-steroidal anti-inflammatory (NSAID) drugs

If any of these apply to you, talk to your doctor, dentist or pharmacist.

**Taking other medicines**

Tell your doctor, dentist or pharmacist before using Difflam Oral Rinse if you are taking any other medicines, even medicines obtained without a prescription.

**Pregnancy and breastfeeding**

If you are pregnant, trying to become pregnant or breast-feeding ask your doctor, dentist or pharmacist for advice before using Difflam Oral Rinse.

This medicine contains glycerol which may cause headache, stomach upset and diarrhoea.

This medicine contains only a small amount of ethanol (alcohol). Each 15 ml of solution contains 1.5 ml of ethanol.

**3. How to use Difflam Oral Rinse**

**Important:**

Always use Difflam Oral Rinse exactly as your pharmacist has told you. You should check with your doctor, dentist or pharmacist if you are not sure.

**If you get Difflam Oral Rinse in your eyes**

Do not use Difflam Oral Rinse in or near your eyes. **If any Oral Rinse gets in your eyes, wash them immediately with cold water.**

**How much Difflam Oral Rinse to use**

- **Adults, adolescents and elderly:** The usual dose is 15 ml of solution to be used every 1½ to 3 hours. Use the measuring cup provided to measure the dose.
- **Children:** This medicine is not suitable for children aged 12 years or under.

**How to use the Oral Rinse**



The solution should be rinsed around the mouth or used as a gargle for 20 to 30 seconds and then spat out.

This solution should not be swallowed.

This solution should not be used for more than 7 days unless your doctor or dentist tells you to.

**If your symptoms worsen or do not improve  
Contact your doctor or dentist if your  
symptoms worsen or they do not improve.**

**If you use more Difflam Oral Rinse than  
you should**

It should not cause you any problems if you accidentally take too much or you swallow some of your medicine. If you have any concerns, contact your doctor or pharmacist.

**If you forget to use Difflam Oral Rinse**

Do not take a double dose to make up for a missed dose. Simply take the next dose as planned.

If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines Difflam Oral Rinse can cause side effects, although not everybody gets them.

**You may experience the following:**

- Severe allergic reaction (anaphylaxis)
- Itching
- Skin rash
- Skin redness or swelling
- Difficulty breathing and wheezing
- Numbness or stinging in the mouth or throat.

If this solution stings your mouth, the next dose can be diluted with some water to reduce this effect.

Some people may react after using the product with a severe allergic reaction experiencing symptoms as described above (a so called anaphylactic reaction) which may be potentially life-threatening. In this case you should seek immediate medical assistance.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Difflam Oral Rinse

Keep out of the reach and sight of children.

Do not use Difflam Oral Rinse after the expiry date on the bottle. The expiry date refers to the last day of that month.

Store in an upright position. Do not store above 30°C. Do not store in the refrigerator or freezer. If you store the product without the original carton, make sure it is kept out of direct sunlight.

Medicines should not be disposed of via wastewater or household waste. Return any medicine you no longer need to your pharmacist.

#### 6. Further information

**What Difflam Oral Rinse contains**

The active substance is benzydamine hydrochloride. Each 15 ml contains 22.5 mg benzydamine hydrochloride.

The other ingredients are ethanol, glycerol, saccharin sodium, mouthwash flavour 52 503/T, polysorbate 20, methyl hydroxybenzoate, Quinoline Yellow (E104) and Patent Blue V (E131), purified water.

For advice on what to do if you are allergic to any of these ingredients see section 2.

**What Difflam Oral Rinse looks like**

It comes in a 300 ml bottle with a metal screw cap and a 20 ml graduated, plastic measuring cup.

**Marketing Authorisation Holder**

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read or you would like it in a different  
format, please contact Meda  
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